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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,466	04/16/2004	William H. Andrews	SIER-022CON	1298
24353	7590	12/05/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			NOBLE, MARCIA STEPHENS	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/826,466

Applicant(s)

ANDREWS ET AL.

Examiner

Marcia S. Noble

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 48, 49 and 53-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46, 48, 49 and 53-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO 413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2006 has been entered.

Status of Claims

1. Claims 46, 48, and 53-61 are pending. Claims 1-45, 47, and 50-52 were canceled previously. Claims 46, 48, 55, 56, and 59 are amended by Applicant's response filed 10/10/2006. Claims 46, 48, 49, and 53-61 are under consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 46, 48, and 49 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-16 of copending Application No. 11/198,933. Although the conflicting claims are not identical, they are not patentably distinct from each other because the breadth of the claims from both applications encompass the same embodiments.

Applicant has submitted a Terminal Disclaimer, filed 8/8/2006, pending allowance of claims 1-4 and 6-16 of the copending application, 11/198933, before the allowance of claims 46, 48, and 49 of the instant application to overcome an obvious-type double patenting rejection is acknowledged.

Claim Rejections - 35 USC § 112, 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 46, 48, 49, and 50-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

while being enabling for:

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a method of determining whether an agent inhibits GC-Box 5 repression of TERT transcription, said method comprising: (a) contacting said agent with a first expression system comprising a GC-Box repressor binding site and a coding sequence operably linked to a TERT promoter under conditions such that in the absence of said agent transcription of said coding sequence is repressed; (b) contacting said agent to a second expression system comprising the said coding sequence of step (a) operably linked to a TERT promoter that does not comprise a GC Box 5 repressor binding site; (c) determining whether transcription of said the coding sequence from the first expression system is repressed in the presence of said agent and determining whether transcription of said the coding sequence from the second expression system is repressed in the presence of said agent, and (d) identifying said agent as an agent that inhibits GC-Box 5 repression of TERT transcription of the coding sequence from the first expression system is not repressed in the presence of the agent and transcription of the coding sequence of the second expression system is not altered in the presence of the agent,

does not reasonably provide enablement for:

The above disclosed invention using first and second expression systems that comprise two different coding sequences.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use/make the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claims encompass a screening method that uses a first expression system comprising the GC Box 5 repressor binding element and a coding sequence operablely linked to a TERT promoter and a second expression system comprising a different coding sequence than the coding sequence of the first expression system sequence operablely linked to a TERT promoter.

However, in a properly controlled screening assay as claim, the control expression system, represented in the instant method as the second expression

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system, and the test expression system represented in the instant method as the first expression system, should have the exact same elements minus the factor that is being tested, which in the instant method is the GC Box 5 repressor binding element. This identity in the non-testing elements in the control and test expression vectors, will provide information about how an agent affects the test element, GC Box 5 repressor binding element, is being affected by an agent without introducing any other variables that may influence the outcome of the method. However, the breadth of the claims encompasses differences in the coding sequences that could result in differences in transcription that are not due to the agent affecting the GC Box 5 repression element as intended. Therefore not providing a nexus between the GC Box 5 repressor element and the test agent. Therefore, an artisan would not know how to use the instant method using two different coding sequences because an artisan would not know if the agent produced its effect through the GC Box 5 repressor element or some other factor that was different about the coding sequences. Therefore, the instant invention is only enabled to use the same coding sequences in both the first and second expression systems.

Response to Amendment

Applicant traversed the enablement rejection of the Final Office Action, mailed 4/10/2006, on the grounds that the amendments to the claims now provided a nexus between the GC Box repressor element and the identification of an agent that inhibits GC Box 5 repression of the TERT promoter. This argument was found to be partially persuasive. The instant method now does provide some embodiments that provide a

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nexus between the GC Box repressor element and the identification of an agent that inhibit GC Box 5 repression of the TERT promoter, but the breadth of the claims also provide embodiments that will not a nexus between the GC Box repressor element and the identification of an agent that inhibit GC Box 5 repression of the TERT promoter and therefore, they are not enabled, as described above.

Claim Rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 46, 48, 49, and 53-61 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: determining whether transcription of said the coding sequence from the second expression system is repressed in the presence of said agent. This test is necessary to compare the first and second expression systems.

5. No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble
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ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER